

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

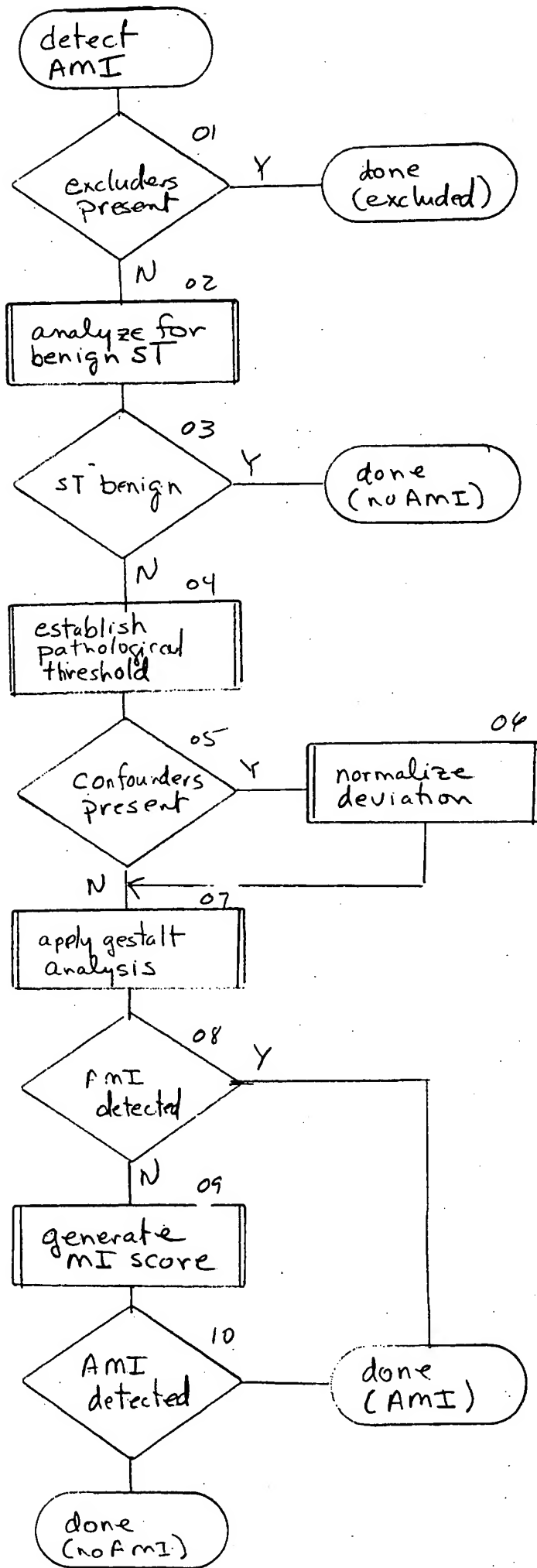


Fig. 1

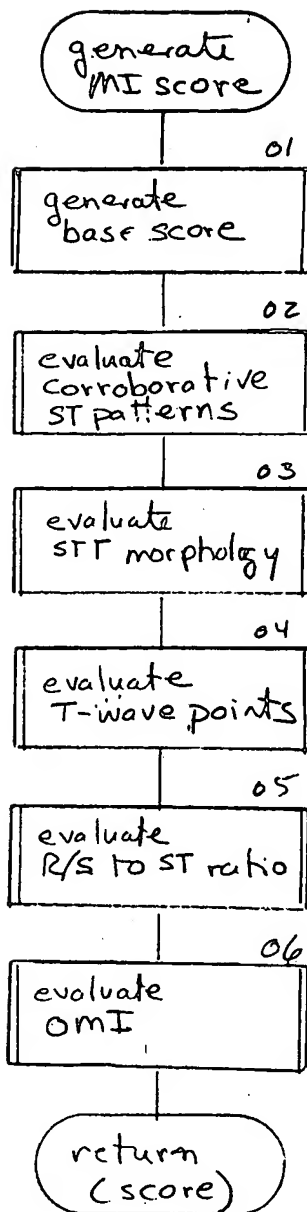


Fig. 2

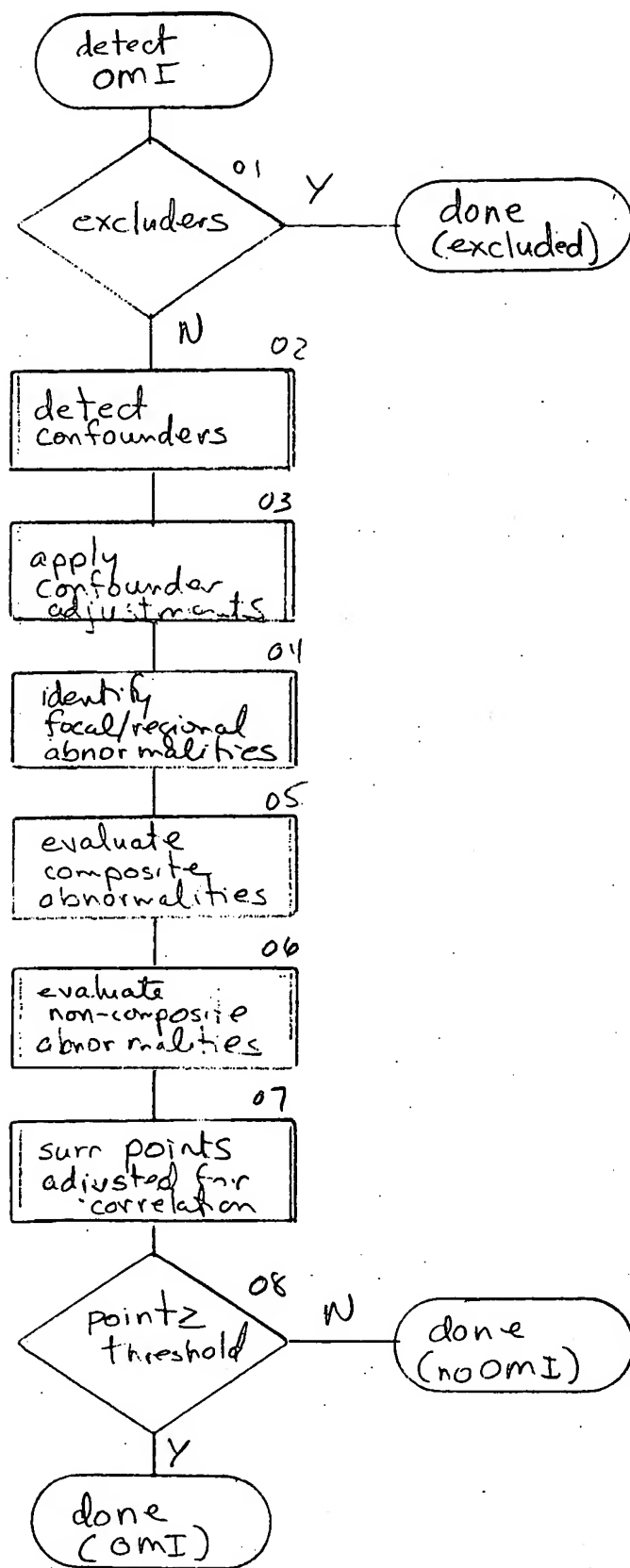


Fig 1

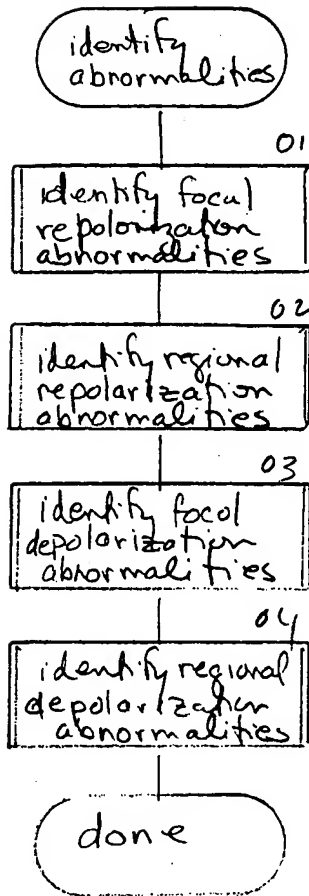


Fig 2

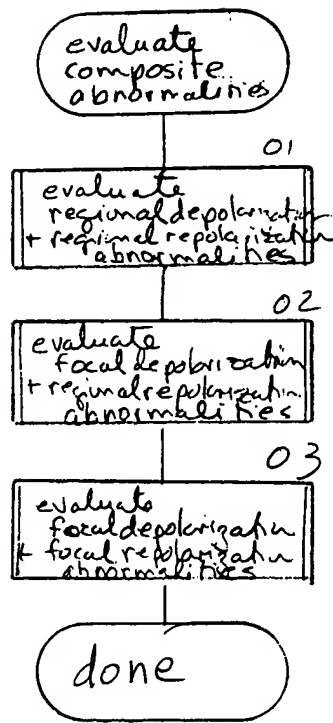


Fig. 3

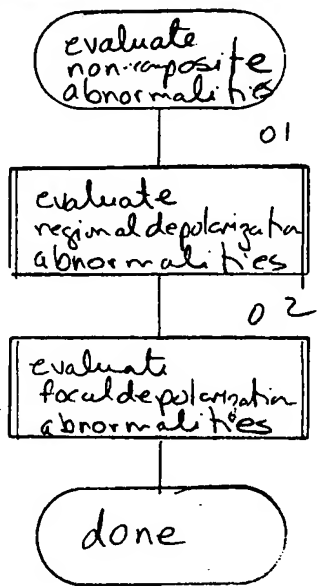


Fig 4

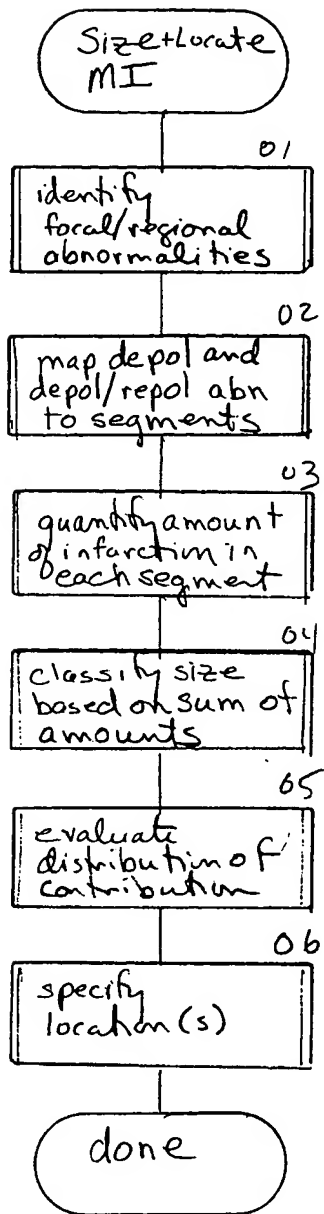


Fig 5



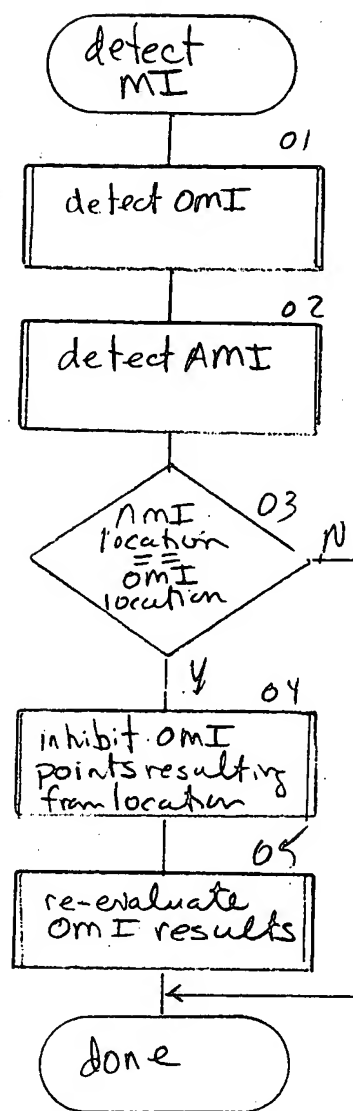


Fig 7

Differentiating Acute Myocardial Infarction  
From Other ECG Abnormalities

Alan Andresen, Ronald Selvester M.D.

Inovise Medical, Inc.

## Clinical Relevance

(Incidence of confounders, difficulty in diagnosis of acute MI)

- LBBB ~5%; Vpacing ~9%
  - Very confusing for overreading clinician; often ignored
- RBBB ~6%
  - Guidelines not adjusted for this confounder (esp. anterior MI)
- LVH ~20% (by conventional ECG criteria)
  - LVH changes on ECG confounder for both sensitivity and specificity (esp. anterior MI)
- Inferior MI w/RV involvement
  - ~40% of RCA occlusions involving RV, with 8x relative risk
  - Clinician identification highly variable; absent for algorithms
- Non-STE ~60% of AMI
  - Borderline STE in this population ~2x for females as compared to males

# ECG Algorithm Confounder Performance

Long Beach AMI. n=1151, CK-MB  $\geq$  9 for rule-in

Method	LBBB n=52	RBBB n=90	LVH n=114	RVH n=27	V-pacing n=55	STE- Female n=263	RV ext n=64
Sensitivity	15%	56%	46%	52%	~15%	29%	~80%
CV	2%	31%	11%	30%	-	7%	-
Alg 1	-	29%	25%	19%	-	10%	-
Alg 2	-	29%	25%	48%	-	17%	-
Alg 3	-	29%	25%	48%	-	17%	-

# ECG Algorithm Confounder Performance

MCV AMI, n=1274, CKMB/Troponin+ for rule-in

Method	LB	BB	RVH	V-pacing	STE- Female	RV ext
Sensitivity	n=26	n=39	n=265	-	n=405	-
CV	12%	38%	26%	-	15%	-
Alg 1	4%	31%	6%	-	7%	-
Alg 2	-	-	-	-	-	-
Alg 3	-	10%	19%	-	9%	-

## AMI Criteria When RBBB+

- Adjust ST deviation to remove portion of STT abnormality due to block
  - ST baseline adjusted by 10% of difference between max and min amplitudes of final 1/3 of QRS complex
- Suppress detection of AMIs that are unseparable from RBBB
  - Posterior (-V1 to -V3, V6)

## AMI Criteria When LBBB+

- Adjust ST deviation to remove portion of STT abnormality due to block
  - ST baseline adjusted by 10% of difference between (Rmax-STJ20) and (Smax-STJ20)
- Adjust STE deviation threshold for calling acute
  - Limb leads: increase by 50 $\mu$ V (100 to 150)
  - Precordial leads: increase by 75 $\mu$ V (200 to 275)
- Suppress detection of acute MIs that are unseparable from LBBB
  - Anterior (V1-V5)
  - Subendocardial injury
- Add qualifiers to improve specificity
  - Posterior AMI only when non-adjusted depression present in V1-V3

## AMI Criteria With ECG Evidence for LVH

- Adjust ST deviation to remove portion of STT abnormality due to "LVH with Repol"
  - ST baseline adjusted by 5% of difference between (Rmax-STJ20) and (Smax-STJ20)
- Adjust ST deviation to remove portion of STT abnormality due to "LVH without Repol"
  - Limb: ST baseline adjusted by 2.5% of difference between (Rmax-STJ20) and (Smax-STJ20)
  - Precordial: ST baseline adjust by lead by -50 to +50uV



## Questions for Discussion

- Pursuing AMI detection when confounders present
  - Is there a consensus about clinical relevance?
  - Is it possible to distinguish these confounders from AMI?
  - Are females significantly under-diagnosed for STE AMI?
- If yes to the above...
  - Which is the most important, clinically?
  - Which is the most likely to yield to investigation?
- If no...
  - Where should we focus our AMI efforts?